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Filed : November 22, 1999

REMARKS

Claims 1 and 19 have been amended and Claims 15-18 have been canceled without prejudice to the right of the Applicants to pursue broader protection in respect of this application by filing one or more divisional applications at a later date. New Claim 127 have been added. Support for the current amendments can be found in the Specification as filed, for example, on page 4, lines 1-5; page 10, line 24 through page 11, line 8; page 18, line 26 through page 19, line 5, and page 42, Example 4. No new matter has been introduced. As a result, Claims 1-14, 18-20, 75, and 124-127 are presented for the examination. The following addresses the substance of the Office Action.

Claim rejections under 35 USC §112

The Examiner has maintained rejections of Claims 1-20, 75, and 124-126 under 35 USC §112, first paragraph. More specifically, the Examiner maintains that the Specification does not provide evidence of a *Leptospira* bacterium that: a) is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession No. N95/69684; b) cross-agglutinates with share group antigens of the *Leptospira fainei* strain WKID deposited under AGAL Accession No. N95/69684, and does not cross-agglutinate with the members of other *Leptospira* groups; or c) belongs to the species *Leptospira fainei* and comprises genomic DNA which is at least 40% homologous to the DNA derived from *Leptospira fainei* strain WKID deposited under AGAL Accession No. N95/69684. The Examiner also alleges that Claims 15-18 fail to meet written description requirement as there is no disclosure of nucleotide sequences with 80% identity to SEQ ID NOs: 1-2 and 4-7. The Applicants have now canceled claims 15-18 and amended Claim 1 to recite a bacterium which comprises a genetic sequence selected from the group consisting of: a) SEQ ID NO: 1; b) sequences having at least 99% identity to SEQ ID NO: 1, and c) sequences complementary to the foregoing sequences, wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession No. N95/69684. Support for the amendment can be found in the Specification as filed on page 8, lines 17-19. Therefore, the current rejection of Claims 1-20, 75, and 124-126 under 35 USC §112, first paragraph does not apply and is respectfully requested to be withdrawn.

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The Examiner has maintained the rejection of Claims 1-20, 75, and 124-126 under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the invention was filed, had possession of the claimed invention. More specifically, the Examiner alleges that, although the Applicants were in possession of the specific *Leptospira* bacterial strain WKID, they were not in possession of additional bacterial strains. The Applicants respectfully maintain, that they were, in fact, in possession of number of strains identified as serovar Hurstbridge including the *Leptospira* strains WKID and BUT6 described in the Specification as filed on page 5, lines 20-24. However, the Applicants have now amended Claim 1 to include the reference to SEQ ID NO: 1 which relates to the nucleotide sequence of the rRNA gene of an isolate of serovar hurstbridge or serogroup Hurstbridge or *L. fainei* (see page 8, lines 17-19 of the Specification as filed). Therefore, the current rejection of Claims 1-20, 75, and 124-126 under 35 USC §112, first paragraph does not apply and should be withdrawn.

The Examiner has maintained the rejection of Claims 1-20, 75, and 124-126 under 35 USC §112, first paragraph, as non-enabled. More specifically, the Examiner has maintained that the Applicants had not made or used the isolated bacterium that a) is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession No. N95/69684; b) cross-agglutinates with share group antigens of the *Leptospira fainei* strain WKID deposited under AGAL Accession No. N95/69684, and does not cross-agglutinate with the members of other *Leptospira* groups; or c) belongs to the species *Leptospira fainei* and the bacterium comprises genomic DNA which is at least 40% homologous to the DNA derived from *Leptospira fainei* strain WKID deposited under AGAL Accession No. N95/69684. The applicants have now amended Claim 1 to recite a bacterium which comprises a genetic sequence selected from the group consisting of: a) SEQ ID NO: 1; b) sequences having at least 99% identity to SEQ ID NO: 1, and c) sequences complementary to the foregoing sequences, wherein said bacterium is cross-reactive in a cross-agglutination absorption assay with the *Leptospira* strain WKID deposited under AGAL Accession No. N95/69684. The Applicants respectfully assert that a person skilled in the art, having the sequencing unifying characteristics of the claimed bacterium as presented in the now amended Claim 1, and in light of the guidance provided in the Specification on how to perform the micro-agglutination assay (page 42,

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Example 4), would not be required to perform undue experimentation to identify and produce an isolated bacterium as claimed in currently amended Claim 1. Therefore, withdrawal of the present rejection of Claims 1-20, 75, and 124-126 is respectfully requested.

The Examiner has rejected Claims 1-20, 75, and 124-126 under 35 USC §112, second paragraph, as being indefinite. More specifically, Claim 1 was rejected for reciting "derived from", "share group antigens"; Claim 19 was rejected for reciting "characteristics of the microorganism deposited...", which the Examiner found indefinite. The Applicants have amended Claim 1 and removed the recited phrases. The Applicants have also amended Claim 19 to now recite specific characteristics of the deposited microorganism, support for which can be found in the Specification as filed (page 10, line 24 through page 11, line 8).

In view of the amendments and arguments presented above, the Applicants respectfully assert that all of the current rejections of Claims 1-20, 75, and 124-126 under 35 USC §112 do not apply and should be withdrawn.

CONCLUSION

Applicants have endeavored to address all of the Examiner's concerns as expressed in the outstanding Office Action. Accordingly, amendments to the claims, the reasons therefor, and arguments in support of the patentability of the pending claim set are presented above. Any claim amendments which are not specifically discussed in the above remarks are made in order to improve the clarity of claim language, to correct grammatical mistakes or ambiguities, and to otherwise improve the capacity of the claims to particularly and distinctly point out the invention to those of skill in the art. In light of the above amendments and remarks, reconsideration and withdrawal of the outstanding rejections is specifically requested. If the Examiner finds any remaining impediment to the prompt allowance of these claims that could be clarified with a telephone conference, the Examiner is respectfully requested to initiate the same with the undersigned.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated:

24 Sept. 2003

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